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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,944	10/04/2001	John L. Herrmann	21402-138 (CURA-438)	3505
30623	7590	05/18/2005	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,944	HERRMANN ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6,9,12-14,39 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6,9,12-14,39 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

B

DETAILED ACTION

Re: Hermann *et al*

1. The amendment filed 2/22/2005 is acknowledged and entered into the record. Accordingly, claims 1-4, 7-8, 10-11, 15-38, and 40-41 are canceled without prejudice or disclaimer.
2. Claims 5-6,9,12-14,39, and 42 are pending and examined on the merits
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections Maintained

4. The objection to the specification for containing embedded hyperlinks is maintained for the reasons of record. The citation of MPEP §608.014 by applicant is duly noted. However, it is unclear if the contents of the page as currently presented is intended to be incorporated as of the filing date or if the applicant intends to incorporate future changes to the contents of the URL. Applicant may overcome this rejection by removing the embedded hyperlinks.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claim 6 under 35 USC § 112, 1st paragraph as lacking adequate written description is maintained for the reasons of record. Applicant argues that the claimed nucleic acid encompasses only the full complement of the claimed sequence. More specifically, applicant argues that the specification teaches that the term

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“complement” is intended to encompass only the full length nucleotide sequence because the specification also makes mention of “portions” or fragments of the claimed sequence. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The term “complement” as interpreted in the claim can encompass both full-length nucleotide sequences or portions/fragments of the claimed nucleotide sequence as previously argued. The applicant points to the specification (page 63, lines 23-27) to support the argument that the term “complement” can only mean full length complements. However, the specification describes nucleotide sequences that are complements of SEQ ID Nos: 1,3,5,7,9, and 11 or portions of SEQ ID Nos: 1,3,5,7,9, and 11. Therefore, the term complement encompasses both full complements (i.e. those that bind to the full length sequence of SEQ ID Nos:1,3,5,7,9, and 11) or partial complements (i.e. those sequences that bind to “a portion” of SEQ ID Nos:1,3,5,7,9,and 11).

Moreover, the specification of the instant application does not support the full breadth of the term “complement”, because the specification has only provided information or disclosure concerning the full length sequence of SEQ ID No: 2, as claimed. The specification does not provided information with regard to substitutions, additions, or modifications to SEQ ID No: 2 or for that matter whether the “complements” of SEQ ID No: 2. Therefore, the written description in this case is only commensurate in scope to the claims that read on SEQ ID No: 2 or full complements of SEQ ID No: 2.

Therefore, the rejection under 35 USC §112, 1st paragraph as lacking proper written description is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 101 &

35 USC § 112, 1st paragraph

6. The rejection of claims 5,6,9,12-14, 39 and 42 under 35 USC §101 as lacking a substantial and specific utility is maintained for the reasons of record. Applicant argues that the instantly claimed invention is supported by a substantial and specific utility. More specifically, applicant argues that NOV1 can be used to differentiate between normal and malignant kidney tissue, and support for this contention, by indicating that methods such as RTQ-PCR can be used to detect and compare the differences in NOV1 expression. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Neither the specification nor any art of record specifically teaches or discloses any specific property of the claimed NOV1 nucleotide sequence. Moreover, the disclosed utility of the NOV1 nucleotide is a general utility that can be applied broadly to any nucleotide sequence, thus the utility disclosed is not particular only to the instantly claimed NOV1 nucleotide. Further, neither the specification nor any art of record provides any descriptive information regarding the claimed nucleotide sequence, such as a nexus between the over-expression NOV1 and neoplastic disease. The specification has not adequately established that over-expression of NOV1 is in fact

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indicative of neoplastic disease and therefore the utility ascribed to the nucleotide sequence is neither substantial nor specific.

Applicant additionally contends that the cited references of Bowie *et al*, Burgess *et al*, Scott *et al*, and Bork *et al* are drawn to the unpredictability of protein function based on homology to known proteins, while the instant invention is drawn to nucleotide sequences. For this applicant concludes that the references are irrelevant and fail to support the rejection under 35 USC §101. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Until some actual and specific significance can be attributed to the protein encoded by the NOV1 nucleotide, the instant invention is incomplete. In the absence of any functional or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a nucleic acid of the instant invention (or the protein encoded thereby) in the diagnosis of kidney cancer would clearly require the use of such as an object of further research, as no such disorders have yet to be identified, and thus would require substantial further investigation, which investigation would constitute part of the inventive process itself. Since the instant specification does not disclose a readily available, real world use for the claimed polynucleotide of the protein encoded thereby, the claimed invention is incomplete and does not meet the requirement of 35 USC § 101 as being useful.

The rejection of claims 5,6,9,12-14, 39 and 42 under 35 USC § 112, 1st paragraph is also maintained. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the

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reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER YAEN
ART UNIT 1642
MAY 16, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/16/03